UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

ARAMIC LLC, et al.,

Plaintiffs,

v.

REVANCE THERAPEUTICS, INC., et al.,

Defendants.

Case No. 21-cv-09585-AMO

ORDER GRANTING DEFENDANTS' MOTION TO DISMISS

Re: Dkt. No. 65

This is a securities fraud case about the U.S. Food and Drug Administration's review of a drug developed by Revance Therapeutics, Inc. ("Revance"). Defendants' motion to dismiss was heard before this Court on August 10, 2023. Having read the papers filed by the parties and carefully considered their arguments therein and those made at the hearing, as well as the relevant legal authority, the Court hereby **GRANTS** the motion to dismiss, for the following reasons.

I. BACKGROUND[1]

Plaintiffs Aramic LLC ("Aramic") and Tang Family Investor Group are stockholders of Defendant Revance Therapeutics, Inc. ("Revance"), who seek to represent purchasers of Revance stock between November 25, 2019, and October 11, 2021 (the "class period"). FAC ¶ 1. Revance is a biotechnology company that develops and sells skin treatment drugs. FAC ¶ 2. During the class period, Defendants made statements regarding the company's attempt to secure U.S. Food and Drug Administration ("FDA") approval for their drug candidate DAXI. FAC ¶¶ 2-3, 7-8. DAXI is a drug used to treat frown lines. FAC ¶ 2.

[1] The Court accepts Plaintiffs' allegations in the complaint as true and construes the pleadings in the light most favorable to Plaintiffs. *See Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir. 2008) (citation omitted).

To obtain FDA approval, drug developers must submit to the FDA a Biologics License Application ("BLA"), which provides testing results, product development information, and descriptions of manufacturing processes. FAC ¶¶ 4, 53. As part of the BLA review process, the FDA typically conducts an inspection to evaluate company compliance with Current Good Manufacturing Practices ("cGMP") regulations, assess readiness for commercial manufacturing, ensure conformance to the submitted application, and ensure the integrity of data submitted with the BLA. FAC ¶¶ 4, 49, 53. After the inspection, the FDA may issue a Form 483 with observations of potential non-compliance with cGMP regulations. FAC ¶¶ 49, 52, 75-76. The company then has fifteen days to respond. FAC ¶ 109. If the FDA does not approve a BLA, it issues a Complete Response Letter ("CRL") explaining why the FDA did not approve the drug. FAC ¶¶ 21, 146.

On November 25, 2019, Revance announced its submission of a BLA for DAXI, which it had been manufacturing since 2010, stating that it anticipated potential FDA product approval at the end of 2020. FAC ¶ 6. Due to COVID-19, the FDA delayed its pre-approval inspection of the manufacturing facility until July of 2021. FAC ¶ 15.

After completing the inspection on July 2, 2021, the FDA provided Revance with a Form 483, containing five "inspectional observations." FAC ¶¶ 74, 77. The first two observations focused on the deterioration of Revance's working cell banks ("WCBs"), which are cell tissues extracted from a repository to produce drug substance and product, and Revance's new WCB not being fully qualified and being a different manufacturing process than proposed in the BLA. FAC ¶¶ 12, 78-81, 87-90. The third observation noted that Revance did not have a "quality agreement" in place with a third-party facility. FAC ¶ 92. The fourth and fifth observations involved how Revance calculated percentage yield and record-keeping details. FAC ¶¶ 97-104.

Revance provided a written response to the Form 483 in July 2021. FAC ¶ 110. It explained that it had enough drug substance from a qualified WCB to support commercial production of DAXI. FAC, Ex. C (ECF 58-3) (Form 483 Response) at 10. Revance also explained that it planned to qualify the new WCB, and believed that qualification was a "post approval activity." *Id.* To that end, Revance stated that it "fully understands that the current WCB

aged and our new WCB will not be fully qualified at the licensure. However, we have a fully functional [redacted] that can last for more than [redacted] as well as [drug substance] inventory to support [drug product] production through [redacted]. Given that supply shortage is not a concern, Revance proposes to submit a post approval application for the WCB qualification package per approved protocol once available. . . [.]" *Id.* at 10-11. Revance also disagreed with the FDA observation that it was using a different manufacturing process than that proposed for licensure. *Id.* at 7.

To address the remaining observations, Revance executed a quality agreement with third-party facility on July 16, 2021, adjusted the way it calculated percentage yield, and amended its record-keeping details and photo clarity. Ex. C at 12-14, 17-18. On August 5, 2021, Revance issued a press release stating that the FDA initiated its pre-approval inspection in June and that Revance anticipated approval of DAXI in 2021. FAC ¶ 150. On October 15, 2021, the FDA issued a Complete Response Letter ("CRL") denying Revance's BLA for DAXI. FAC ¶ 168. On March 8, 2022, Revance resubmitted its BLA. FAC ¶ 175. In September 2022 after issuance of another Form 483 in March 2022, the FDA approved DAXI. FAC ¶¶ 178-79.

On December 10, 2021, Plaintiffs filed the instant securities class action. ECF 1. On November 7, 2022, Plaintiff filed the operative complaint, the First Amended Complaint ("FAC") against Defendants Mark Foley, Tobin Schilke, and Abhay Joshi ("Individual Defendants") and Revance (collectively, "Defendants") alleging that Defendants made 29 false or misleading statements about the timing and likelihood of FDA approval of DAXI in violation of Sections 10(b) and 20(a) of the Exchange Act in the following general categories:

> (1) Defendants failed to disclose significant quality control and manufacturing deficiencies that made FDA approval unlikely;
>
> (2) Defendants' statements about readiness for FDA inspection and confidence in FDA approval were false and misleading given the deficiencies that existed; and
>
> (3) Defendants continued statements expressing confidence in FDA approval after the Form 483 was issued were false and misleading.

See FAC (ECF 58) ¶¶ 7, 269-84. On January 23, 2023, Defendants filed a motion to dismiss the

complaint under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted. Motion (ECF 65).

II. LEGAL STANDARD

Federal Rule of Civil Procedure 8(a) requires that a complaint contain "a short and plain statement of the claim showing that the pleader is entitled to relief." A defendant may move to dismiss a complaint for failing to state a claim upon which relief can be granted under Federal Rule of Civil Procedure 12(b)(6). "Dismissal under Rule 12(b)(6) is appropriate only where the complaint lacks a cognizable legal theory or sufficient facts to support a cognizable legal theory." *Mendiondo v. Centinela Hosp. Med. Ctr.*, 521 F.3d 1097, 1104 (9th Cir. 2008). To survive a Rule 12(b)(6) motion, a plaintiff must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim is facially plausible when a plaintiff pleads "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

In reviewing the plausibility of a complaint, courts "accept factual allegations in the complaint as true and construe the pleadings in the light most favorable to the nonmoving party." *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir. 2008). Nonetheless, Courts do not "accept as true allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." *In re Gilead Scis. Secs. Litig.*, 536 F.3d 1049, 1055 (9th Cir. 2008).

Securities fraud cases have heightened pleading requirements as the complaint must satisfy both the pleading requirements of Federal Rule of Civil Procedure 9(b) and the PSLRA. *In re VeriFone Holdings, Inc. Sec. Litig.*, 704 F.3d 694, 701 (9th Cir. 2012). Pursuant to Rule 9(b), claims alleging fraud must "state with particularity the circumstances constituting fraud…" Fed. R. Civ. P. 9(b). The PSLRA mandates that "the complaint shall specify each statement alleged to have been misleading, [and] the reason or reasons why the statement is misleading. . . [.]" 15 U.S.C. § 78u–4(b)(1)(B). The PSLRA further requires that the complaint "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 314 (2007) (quoting

15 U.S.C. § 78u–4(b)(2)(A)). This means a plaintiff must allege that "the defendant[] made false or misleading statements either intentionally or with deliberate recklessness." *In re VeriFone Holdings*, 704 F.3d at 701 (quoting *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 991 (9th Cir. 2009)).

Section 10(b) of the Securities Exchange Act makes it unlawful for any person to "use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors." 15 U.S.C. § 78j(b). SEC Rule 10b-5 implements this provision, making it unlawful to, among other things, "make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading[.]" 17 CFR § 240.10b–5(b).

III. DISCUSSION

A. Request for Judicial Notice

While the scope of review on a motion to dismiss is generally limited to the contents of the complaint, courts may take judicial notice of facts that are "not subject to reasonable dispute." Fed. R. Evid. 201(b). Courts may consider documents incorporated into the complaint by reference, *Tellabs*, 551 U.S. at 322, and take judicial notice of documents on which complaints necessarily rely, *Lee v. City of Los Angeles*, 250 F.3d 668, 688 (9th Cir. 2001), publicly available financial documents such as SEC filings, *Metzler Inv. GMBH v. Corinthian Colls., Inc.*, 540 F.3d 1049, 1064 n.7 (9th Cir. 2008), and publicly available articles or other news releases of which the market was aware, *Heliotrope Gen., Inc. v. Ford Motor Co.*, 189 F.3d 971, 981 n.18 (9th Cir. 1999). The Court may not assume the truth of an incorporated document "if such assumptions only serve to dispute facts in a well-pleaded complaint." *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 1003 (9th Cir. 2018).

Defendants seek judicial notice of 27 exhibits. They argue that 23 exhibits including press releases, SEC filings, conference call and investor presentation transcripts, and documents issued to the FDA, are incorporated by reference in the FAC as they are "extensively referenced in the

Complaint or otherwise form the basis of Plaintiff's claims." RJN (ECF 66) at 7. Plaintiffs agree that Exhibits 2-17, 20, and 22-26 (press releases, earnings call and presentation transcripts, and SEC) are incorporated by reference, but may not be considered for their truth. ECF 69 at 15. Accordingly, the Court takes judicial notice of the incorporated documents but does not assume the truth of disputed facts. *See Khoja*, 899 F.3d at 1003.[2]

Exhibit 19, a publicly available FDA guidance document, is also the proper subject of judicial notice. "[C]ourts routinely take judicial notice of [ ] FDA guidance documents, many of which also appear on the FDA's public website." *Immanuel Lake v. Zogenix, Inc.*, No. 19-CV-01975-RS, 2020 WL 3820424, at *5 (N.D. Cal. Jan. 27, 2020) ("*Zogenix*") (citation omitted). Because the document is accessible on the FDA's website (specifically, at https://www.fda.gov/media/109615/download) as of the date of this order, its "accuracy cannot reasonably be questioned," making it subject to judicial notice. Fed. R. Evid. 201(b).

Plaintiffs object to the Court taking judicial notice of Exhibits 1 (Review of Post-Inspection Responses), 18 (Revance's Form 8-K filed with the SEC on May 26, 2021), and 27 (September 8, 2022 press release). ECF 69 at 17-19. Exhibits 1 and 18 are each referred to once in the FAC, in passing reference, and do not form the basis of Plaintiffs' claims. *See* FAC ¶¶ 69, 109. Plaintiffs cite Exhibit 27 once in their FAC to discuss that the FDA approved Revance's BLA for DAXI in September 2022, FAC ¶ 179, but argue that the eventual approval is not relevant to their claims. Because these exhibits do not form the basis of Plaintiffs' claims, the Court does not take judicial notice of Exhibits 1, 18, or 27.

Defendants argue that Revance's unredacted Form 483 Response, Ex. 21, is incorporated by reference, as Plaintiffs attach the redacted version of the same document to the FAC (*see* ECF 58-3), and the document forms the basis of Plaintiffs' complaint. ECF 66 at 9. Plaintiffs do not

[2] For example, the Court takes judicial notice of the fact that the documents, such as the press releases, contained purportedly cautionary language about forward-looking statements. *See Diversified Capital Invs., Inc. v. Sprint Commc'ns, Inc.*, 2016 WL 2988864, at *4 (N.D. Cal. May 24, 2016) (taking "judicial notice of the existence and facial content of the press release," but not for its truth); *In re Twitter, Inc. Sec. Litig.*, 2020 WL 4187915, at *3 (N.D. Cal. Apr. 17, 2020) ("the court will take judicial notice of the analyst reports, news articles, and SEC filings cited by [p]laintiffs, but not for the truth of the matters asserted therein.").

dispute the accuracy or authenticity of the unredacted Form 483 Response but argue that it is not incorporated by reference as it is not referred to extensively and does not form the basis of Plaintiffs' claims. The Court agrees. Plaintiffs refer to the Form 483 Response on three occasions in the FAC. *See* FAC ¶ 15 (explaining that Revance was able to address "minor deficiencies the FDA identified" but could not address the ineffectiveness of the WCB and "incorrectly claim[ed] that it was using 'the exact same process as proposed'"); ¶ 84 (Revance initiated a quality investigation in September 2020 that determined in December 2020 that the root cause of the issue was the effectiveness of the previously qualified WCB); *see also* FAC ¶ 110. However, Revance's Form 483 Response does not form the basis of Plaintiffs' claims as the document "creates a defense to the" FAC's allegations and Plaintiffs did not have access to the unredacted document. *See Khoja*, 899 F.3d at 1001-02. Accordingly, the Court finds that Ex. 21 is not incorporated by reference.

B. Motion to Dismiss

Defendants move to dismiss the FAC, arguing that the challenged statements are not actionable because they are forward-looking statements protected by the PSLRA safe harbor or are corporate puffery or opinion statements. Defendants further assert that any remaining statements are not false or misleading or were made without scienter. The Court considers each argument in turn.

1. Forward-Looking Statements

Under the PSLRA's "safe harbor" rule, a person is not liable for a false or misleading "forward-looking statement" if 1) it is "accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially" or 2) the forward-looking statement is "immaterial" or 3) the plaintiff fails to prove it is made by a natural person with "actual knowledge . . . that the statement was false or misleading." 15 U.S.C. § 78u-5(c); *see Weston Fam. P'ship LLLP v. Twitter, Inc.*, 29 F. 4th 611, 620 (9th Cir. 2022). A forward-looking statement is "any statement regarding (1) financial projections, (2) plans and objectives of management for future operations, (3) future economic performance, or (4) the assumptions 'underlying or related to' any of these issues." *No. 84 Emp.-Teamster Joint Council Pension Tr.*

Fund v. Am. W. Holding Corp., 320 F.3d 920, 936 (9th Cir. 2003) (citing 15 U.S.C. § 78u-5(i)).

Defendants argue that these statements expressing anticipation of future FDA approval are forward-looking statements protected by the PSLRA safe harbor:

- "Revance anticipates potential product approval in the second half of 2020." FAC ¶ 115 (Nov. 25, 2019 Press Release).
- "Revance anticipates acceptance of the submission in the first quarter and projects potential approval in the fourth quarter of 2020." FAC ¶¶ 116 (January 9, 2020 Press Release), 118 (Feb. 6, 2020 Press Release).
- "We continue to anticipate approval this year and, as we have noted before, the FDA did not indicate that there were any other review issues beyond the pending inspection." FAC ¶ 143 (May 10, 2021 Press Release).
- "Revance continues to anticipate receiving approval for [DAXI] in 2021 and is actively building inventory and preparing for commercial launch." FAC ¶ 150 (Aug. 5, 2021 Press Release), ¶ 155 (Aug. 5 2021 Earnings Call).
- "[T]he company continues to anticipate FDA approval of [DAXI] . . . in 2021." FAC ¶ 165 (Oct. 12, 2021 Press Release).

Plaintiffs do not dispute that these statements about the likelihood of FDA approval are forward-looking. Opposition (ECF 68) at 24-24; *see Kovtun v. VIVUS, Inc.*, No. C 10-4957 PJH, 2012 WL 4477647, at *12 (N.D. Cal. Sept. 27, 2012) ("*VIVUS*"), *aff'd sub nom. Ingram v. VIVUS, Inc.*, 591 F. App'x 592 (9th Cir. 2015) ("Projections about the likelihood of FDA approval are forward-looking statements. They are assumptions related to the company's plan for its product, and as such fall under the PSLRA's safe harbor rule."). Instead, Plaintiffs argue that the statements were not accompanied by meaningfully cautionary language or were made with actual knowledge of their falsity. Opposition at 24-25.

Statements that Defendants made prior to the July 2021 FDA inspection were accompanied by cautionary language. Defendants repeatedly warned investors that forward-looking statements are "subject to risks and uncertainties that could cause actual results to differ materially from our expectations," Ex. 3 (ECF 65-4) (Jan. 9, 2020 Press Release) at 3, Ex. 4 (ECF 65-5) (Feb. 6, 2020 Press Release) at 2, such as the "ability to obtain and maintain regulatory approval of our drug product candidates," Ex. 2 (ECF 65-3) (Nov. 25, 2019 Press Release) at 1, Ex. 3, Ex. 4, and the

"results, timing . . . and development activities and regulatory approvals, including the continuing delay in the FDA's approval of the BLA for [DAXI], including as a result of delays in the site inspection conducted of our manufacturing facility . . . [and] observations made by the FDA during the site inspection . . . due to COVID-19 . . . observations made by the FDA during the site inspection and other reasons. . . [.]" Ex. 16 (ECF 65-17) (May 10 2021 Press Release) at 4, Ex. 22 (ECF 65-22) (Aug. 5, 2021 Press Release) at 4 (same).

Plaintiffs acknowledge that they "are not [] alleging that [Defendants] filed a BLA they knew could never be approved." Opposition at 10. Instead, they argue that the cautionary statements were "boilerplate" as they fail to mention the actual risks facing BLA approval, such as the ineffective WCB, the possibility of a CRL, and the issuance of the Form 483. *Id.* at 24-25. However, Plaintiffs have not shown that prior to the issuance of the Form 483, and prior to Revance determining the root cause of the rejected lots, Defendants believed or had reason to believe that their projections of the timeline for BLA approval were inaccurate. Indeed, courts have found less detailed cautionary statements to sufficiently caution investors. *See, e.g., Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc.*, 759 F.3d 1051, 1059-60 (9th Cir. 2014) ("*Intuitive Surgical*") ("Actual results may differ materially from those expressed or implied, as a result of certain risks and uncertainties. These risks and uncertainties are described in detail in the company's [SEC] filings. Prospective investors are cautioned not to place undue reliance on such forward-looking statements."); *In re Cutera Sec. Litig.*, 610 F.3d 1103, 1112 (9th Cir. 2010) ("[T]hese prepared remarks contain forward-looking statements concerning future financial performance and guidance . . . management may make additional forward-looking statements in response to questions, and . . . factors like Cutera's ability to continue increasing sales performance worldwide could cause variance in the results."). Thus, the pre-inspection statements anticipating approval within a projected timeline are immunized. *See* FAC ¶¶ 115, 116, 143.

Plaintiffs also challenge the cautionary language as insufficient once Defendants received the Form 483. For example, on August 5, 2021, Revance issued a press release stating that it anticipated FDA approval in 2021. FAC ¶ 150. The press release included a warning that forward-looking statements involved risks such as "the continuing delay in the FDA's approval of

the BLA for [DAXI] . . . , including as a result of observations made by the FDA during the site inspection . . . [.]" Ex. 22 at 4. Although the press release warns of the risk of delay due to FDA observations, Plaintiffs argue that it does not caution investors of the risks that were already realized – the rejected drug substance lots, that WCB qualification was not projected to be complete until December 31, 2021, and the FDA had informed the company that its manufacturing changes were inconsistent with the submitted BLA. FAC ¶¶ 86-87 (citing Ex. B at 22), 193. Determining whether this language is meaningfully cautionary is a closer call. *Cf. In re Solarcity Corp. Sec. Litig.*, 274 F. Supp. 3d 972, 993 (N.D. Cal. 2017) (warning language was meaningful where it "specifically refers to a potential lack of demand and the potential that signed contracts would be cancelled, the two risk factors that Plaintiffs allege that Defendants failed to disclose").

Nonetheless, even if the language was not meaningfully cautionary, the statements are protected under the safe harbor as Plaintiffs have failed to allege "with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind," that is, "actual knowledge . . . that the statement was false or misleading." 15 U.S.C. § 78u–4(b)(2); 15 U.S.C. § 78u–5(c)(1)(B)(i); *see In re Cutera*, 610 F.3d at 1113. Plaintiffs argue that Defendants knew that the ineffective WCB and Form 483 decreased the likelihood of BLA approval. Opposition at 25. Although in hindsight, the projections may have been overly optimistic, Plaintiffs have not alleged that Defendants knew that the projected timeline for BLA approval was not possible. *See, e.g., In re Connetics Corp. Sec. Litig.*, 542 F. Supp. 2d 996, 1008 (N.D. Cal. 2008) (statements predicting that the "FDA would approve [the drug] were not made in the face of actual knowledge that [the drug] could never be approved; rather, they may have been made in the optimistic belief that the transgenic testing problem was a surmountable barrier to FDA approval"). Defendants may have reasonably believed that they could fix any deficiencies by the timeline they predicted. *See In re Syntex Corp. Sec. Litig.*, 95 F.3d 922, 930 (9th Cir. 1996) ("Syntex was forecasting a future event. Any alleged deficiencies in the testing procedures do not indicate that Syntex's prediction of an FDA approval date was false when made. Instead, the company could have known of problems in the testing procedures, planned to remedy those deficiencies, and still thought it would achieve FDA approval by the estimated date."). Indeed, Defendants' Form 483 Response shows that they

informed the FDA that they considered (Plaintiffs argue wrongfully so) WCB qualification to be a post-approval activity. Ex. C at 10-11. Thus, Plaintiffs have not shown actual falsity, and the statements about the anticipated timeline for DAXI approval are protected under the PSLRA safe harbor. Accordingly, the Court **DISMISSES** the Section 10(b) claim with respect to the statements about the anticipated timeline for DAXI approval.

2. Corporate Optimism and Opinion Statements

Defendants also argue that Plaintiffs challenge vague statements of optimism and opinion statements that are not actionable. In the Ninth Circuit, "vague, generalized assertions of corporate optimism or statements of 'mere puffing' are not actionable material misrepresentations under federal securities laws" because no reasonable investor would rely on such statements. *City of Royal Oak Ret. Sys. v. Juniper Networks, Inc.*, 880 F. Supp. 2d 1045, 1063 (N.D. Cal. 2012) (quoting *In re Impac Mortg. Holdings, Inc. Sec. litig.*, 554 F. Supp. 2d 1083, 1096) (citing *Glen Holly Entm't, Inc. v. Tektronix, Inc.*, 352 F.3d 367, 379 (9th Cir. 2003)); *see In re Cutera*, 610 F.3d at 1111 ("professional investors, and most amateur investors as well, know how to devalue the optimism of corporate executives") (citation omitted). This is because "[w]hen valuing corporations, . . . investors do not rely on vague statements of optimism like 'good,' 'well-regarded,' or other feel good monikers." *In re Cutera*, 610 F.3d at 1111. However, even "general statements of optimism, when taken in context," may be misleading "when those statements address specific aspects of a company's operation that the speaker knows to be performing poorly." *In re Quality Sys., Inc. Sec. Litig.*, 865 F.3d 1130, 1143 (9th Cir. 2017) (citation omitted).

Expressions of opinions – as opposed to statements of fact – are only actionable if they are both subjectively and objectively false or misleading. *Rubke v. Capitol Bancorp Ltd*, 551 F.3d 1156, 1162 (9th Cir. 2009) (citing *Va. Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1094-96 (1991)). "To be misleading, a statement must be "capable of objective verification.' " *Retail Wholesale & Dep't Store Union Loc. 338 Ret. Fund v. Hewlett-Packard Co.*, 845 F.3d 1268, 1275 (9th Cir. 2017) (quoting *Or. Pub. Emps. Ret. Fund v. Apollo Grp. Inc.*, 774 F.3d 598, 606 (9th Cir. 2014)).

The parties agree that Plaintiffs challenge various opinion statements:

- "the BLA filing represents a monumental achievement . . . Revance enters a catalyst-rich calendar year of significant clinical trial readouts and meaningful Company milestones." FAC ¶ 115 (Nov. 25, 2019 Press Release).
- "This progress has set us up for a transformational 2020, a year which we believe will be characterized by excitement and execution." FAC ¶ 121 (Q4 2019 Earnings Call)
- "This is a very exciting and pivotal year for Revance . . ." FAC ¶ 116 (Jan. 9, 2020 Press Release).
- "The FDA's acceptance of our BLA for our next-generation neuromodulator product, DAXI, is a significant achievement for Revance and a crucial step forward. . ." FAC ¶ 118 (Feb. 6, 2020 Press Release)
- ". . . Revance has constructed an exceptional start to what we believe will be transformational year for the company." FAC ¶ 119 (Feb. 24, 2020 Press Release).
- "[S]hould the anticipated approval of DaxibotulinumtoxinA for Injection in glabellar lines be delayed, we believe that Revance is in a strong position, both commercially and financially, to weather any near-term change in timing. Just as importantly, we remain confident in the overall strength of our BLA submission for [DAXI]." FAC ¶¶ 130 (Nov. 9, 2020 Press Release) 132 (Nov. 9, 2020 Q3 Earnings Call); *see also* FAC ¶ 136 (Jan. 7, 2021 Press Release).
- " . . . we continue to feel very good about the quality of the submission . . ." FAC ¶ 133 (Nov. 9, 2020 Q3 Earnings Call)
- "We feel very good in terms of our preparedness . . . and continue to build product in preparation for launch." FAC ¶ 146 (June 8, 2021 Goldman Sachs Conference).
- "In closing, we're very proud of our performance in the first half of the year and anticipate a strong finish in the second half with the potential approval of [DAXI] . . . we feel very good about our prep and where we were in that process and we continue all of our preparations in the hopeful approval of the product." FAC ¶¶ 155, 157 (Aug. 5, 2021 Q2 2021 Earnings Call).
- "But we feel really good about where we are in that process [for approval of the neuromodulator]." FAC ¶ 159 (Sept. 9, 2021 Wells Fargo Conference).

Here, the Court finds that statements in FAC ¶¶ 115, 116, 118, 119, and 121 are statements of corporate optimism. *See* FAC ¶ 115 (filing the BLA was a "monumental achievement"); FAC ¶ 121 (the year will be full of "excitement and execution"); FAC ¶¶ 116, 119 (it is an

"exciting," "pivotal," and "transformational" year for Revance). These statements are "feel good monikers" that are not actionable. *See In re Cutera*, 610 F.3d at 1111; *see also In re Solarcity*, 274 F. Supp. 3d at 994-95 (finding that the following statements were corporate puffery: "we're highly optimistic . . . about our growth," "[d]emand remained as strong as ever," "Q2 was an amazing quarter," and "I'm very happy with our continued ability to scale and [unbelievably] strong sales"). Plaintiffs argue that these statements are objectively verifiable because Revance was experiencing deficiencies that implicated readiness for BLA approval. Opposition at 23-24. However, they cite no binding or persuasive caselaw in support of their contention that these vague statements of optimism are actionable. For example, Plaintiffs do not explain how the statement that the acceptance of the DAXI BLA is a "significant achievement" and a "crucial step forward" is misleading to investors. *See* FAC ¶ 118. Such "mildly optimistic, subjective assessment[s] . . . [do not] amount to a securities violation." *See In re Cutera*, 610 F.3d at 1111; *see, e.g.*, *Bodri v. GoPro, Inc.*, 252 F. Supp. 3d 912, 924 (N.D. Cal. 2017) (statement that the company was "enjoying terrific momentum" which was a "testament to the strength of the GoPro brand" was corporate optimism even though plaintiffs alleged that sales were weak and within days GoPro had cancelled orders). Accordingly, the statements in FAC ¶¶ 115, 116, 118, 119, and 121 are not actionable.

Next, Plaintiffs argue that pre-inspection statements about Revance's "confidence" in the BLA submission and the "good" feelings about preparedness for inspection were misleading as Defendants knew they had not entered into a Quality Agreement (QA) or failed to disclose that the opinions were formed "without a reasonable inquiry into the BLA's completeness." Opposition at 23. However, as discussed below, the failure to enter into the QA was not material as Defendants were able to remedy it within days of the FDA's observations. Ex. C at 12. Accordingly, Plaintiffs have not shown that the pre-inspection statements that Revance felt "good" or "confident" about the BLA submission and inspection (FAC ¶¶ 130, 132, 133, 136, 146) were false when made.

Finally, Plaintiffs argue that statements made while aware of the rejected lots, the ineffective WCB, and the Form 483 were misleading by omission. Opposition at 22-23. Even

assuming that Revance was not objectively ready for the FDA inspection because of the ineffective WCB, Plaintiffs have not specifically pleaded that prior to the inspection Defendants believed that their confidence in the BLA approval process or readiness for inspection was false. Accordingly, statements in FAC ¶¶ 130, 132, and 133 that Defendants feel "good" and "confident" about the approval process are not actionable. *See In re Siebel Sys., Inc. Sec. Litig.*, No. C 04-0983 CRB, 2005 WL 3555718, at *4 (N.D. Cal. Dec. 28, 2005) ("That a new program has kinks does not make a positive statement about the program false. If that were the case, the federal securities laws would prevent software companies from making any positive statements about new software").

However, during the inspection, the FDA inspector explained that Revance's assumption that the manufacturing changes it made were "consistent with the BLA" was "incorrect." FAC ¶ 193. The Court agrees that at this point, statements that Revance felt good about its preparedness for approval (FAC ¶¶ 155, 157, 159) were misleading given the FDA inspector's explanation. Indeed, after July 2, 2021, even if Defendants "genuinely believed" they were ready for approval, Revance was "aware of undisclosed facts tending seriously to undermine the statement's accuracy." *See City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Align Tech., Inc.*, 856 F.3d 605, 616 (9th Cir. 2017) (citations omitted). At this stage, the Court cannot "conclude that the statement[s] [are] 'so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of their unimportance.' " *In re Energy Recovery Inc. Sec. Litig.*, No. 15-CV-00265-EMC, 2016 WL 324150, at *20 (N.D. Cal. Jan. 27, 2016) (citation omitted). Thus, statements in FAC ¶¶ 155, 157, and 159 may be actionable if Plaintiffs have alleged scienter.

3. Materially False or Misleading

For a statement to be actionable under the PSLRA it must be false or misleading as well as material. "Under Rule 10b-5, . . . a fraudulent omission is a failure to 'state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading.' " *Wochos v. Tesla, Inc.*, 985 F.3d 1180, 1188 (9th Cir. 2021) (quoting 17 C.F.R. § 240.10b-5(b)). A statement is misleading "if it would give a

reasonable investor the 'impression of a state of affairs that differs in a material way from the one that actually exists.' " *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 985 (9th Cir. 2008) (quoting *Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002)).

An omitted fact is material if there is a "substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976). "The inquiry into materiality is 'fact-specific.' " *In re Alphabet, Inc. Sec. Litig.*, 1 F. 4th 687, 700 (9th Cir. 2021) (quoting *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 43 (2011)). As such, "resolving materiality as a matter of law is generally appropriate 'only if the adequacy of the disclosure or the materiality of the statement is so obvious that reasonable minds could not differ.' " *Id.* (citation omitted).

Plaintiffs challenge 29 statements as false and misleading prior to and after the FDA inspection. Defendants argue that Plaintiffs have not adequately alleged the falsity of any specific statement or shown that any statement is misleading and have not alleged that two Defendants made any statements. Defendants distinguish between statements made before the drug substance lots were rejected (August and September 2020), before the FDA inspection and issuance of the Form 483 (July 2021), and after the inspection. The Court considers the arguments below.

a. Pre-Inspection Statements (November 2019 Through August 2020)

Defendants made pre-inspection statements that Revance was "ready" for the FDA inspection and "feel[s] very good about the quality of the submission," FAC ¶ 133, and the FDA "did not indicate there are any other review issues at this time, beyond the on-site inspection," FAC ¶ 135. Plaintiffs argue that these statements are false or misleading given the quality control deficiencies[3] – mainly, the lack of a Quality Agreement ("QA") with a third-party facility, FAC ¶¶ 117, 120, 122, 125, 127, 129. Defendants argue that Plaintiffs have not alleged that any quality control deficiencies, if they did exist, were material, or that they needed to be disclosed.

[3] Plaintiffs admit that the Form 483 Observations 4 and 5 (yield calculations and written procedures) are "minor" deficiencies. Opposition at 16.

Motion at 20-22.

As part of the BLA approval process, Revance was required to enter into a QA with a third-party testing facility. FAC ¶ 94. However, Plaintiffs do not allege that a QA was needed in 2019 or 2020, when these statements were made. Allegations that Revance had leased a testing facility since 2015, FAC ¶ 194, are insufficient to show that a QA was required at the time Revance made statements about readiness for inspection. Further, Plaintiffs only point to the July 2021 Form 483 to demonstrate that a QA was necessary for the BLA. There is a "general principle" that "to be actionable, a statement or omission must have been misleading at the time it was made; liability cannot be imposed on the basis of subsequent events." *Reese v. BP Exploration (Alaska) Inc.*, 643 F.3d 681, 693 (9th Cir. 2011) (internal quotations omitted). Thus, Plaintiffs have not specifically alleged that the 2019 and 2020 readiness statements or projected timelines for approval were false.

Even if a QA was necessary in 2019 or 2020, Plaintiffs have not alleged that the lack of a QA materially decreased the likelihood that the BLA would be approved on Defendants' projected timeline. Materiality requires a "substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of the information available." *Matrixx Initiatives*, 563 U.S. at 38 (citation omitted). Plaintiffs do not dispute that Revance entered a new QA before responding to the Form 483, or that the FDA inspected the third-party facility and identified no issues. Ex. C at 12; FAC ¶ 15. Thus, Plaintiffs have not shown that failure to disclose the lack of a QA made statements about being "ready" or anticipating approval by the end of the year materially misleading.

b. Pre-Inspection Statements (November 2020 Through June 2021)

Plaintiffs challenge the following statements as false or misleading due to the rejected drug substance lots and the ineffective WCB:

- "Though the company's BLA is still under review, the FDA did not indicate any further outstanding review issues beyond the pending on-site inspection. The company remains confident in its BLA submission and continues to work proactively with the FDA on a preapproval inspection as soon as possible in 2021." FAC ¶ 136 (Jan. 27, 2021 Press Release); *see also* FAC ¶¶ 133 (Nov. 9, 2020 Earnings Call), 135 (Nov. 25, 2020 Press Release).

- "We have the ability to manufacture our own botulinum toxin bulk drug substance to support our clinical trial programs and eventually, our commercial production." FAC ¶ 138 (Feb. 25, 2021 10-K).

- "We remain ready to support an on-site inspection as soon as the agency is able to visit our facility. And we continue to build drug product inventory in anticipation of approval and are eager to introduce this unique product into the aesthetics market." FAC ¶ 144 (May 10, 2021 Earnings Call); *see also* FAC ¶ 143.

- "[Approval decision] will be the next update. Obviously if there was something that was not favorable, we would certainly release that, but really the next update would be approval." FAC ¶ 146 (June 8, 2021 Goldman Sachs Conference).

Defendants argue that these statements were not misleading as Plaintiffs have not alleged that the WCB needed to be qualified before obtaining FDA approval and the statements did not trigger a need to disclose that the rejected drug substance lots. Motion at 22-24; *see* Ex. C at 10-11.

While there is no "freestanding completeness requirement," a statement is misleading by omission if it "affirmatively create[s] an impression of a state of affairs that differs in a material way from the one that actually exists." *Brody*, 280 F.3d at 1006. As recognized by the Supreme Court, "whether an omission makes an expression of opinion misleading always depends on context." *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175, 190 (2015). Here, the context was that the WCB produced two drug substance lots that were rejected in August and September 2020, FAC ¶ 81, in September 2020, Revance conducted a quality investigation, and in May 2021 recommended corrective action and preventative action to manufacture and qualify a new WCB with a projected timeline of December 31, 2021 – six months after the pre-approval inspection. FAC ¶ 191.

Prior to May 2021, Revance had not yet determined the WCB was ineffective or would not be qualified until the end of 2021. Further, Revance's Form 483 Response shows that the new WCB "performs as expected" and "consistently met the specification," suggesting that the statement about the ability to manufacture drug substance was not misleading or false when made. Ex. C at 9. *See, e.g.*, *Browning v. Amyris, Inc.*, No. 13-CV-02209-WHO, 2014 WL 1285175, at

*10 (N.D. Cal. Mar. 24, 2014) (statements that the company had created a process with "industrial-scale production" were not false or misleading even if the company missed its production targets, and limited or failed test runs were not inconsistent with statements that the company "expects to begin" production in May).

Plaintiffs argue that by stating it was "ready" for inspection, Revance conveyed the impression "that there was nothing material left to do for the inspection to be successful." Opposition at 16. However, Plaintiffs have not alleged that the WCB needed to be qualified prior to the inspection for Revance to be "ready" for inspection. *See* FAC ¶ 80 (stating only that FDA regulatory guidance requires that a newly prepared WCB be appropriately qualified by characterization and testing); *see, e.g.*, *Zogenix, Inc.*, 2020 WL 3820424, at *8 (finding no falsity where plaintiffs "appear to assume that defendants knew, at the time of filing the [new drug application], that the failure to reference [] toxicity studies made the application facially deficient and created an 'exceedingly high risk' of rejection, but plaintiffs pleaded no specific allegations to support this critical assumption"). Indeed, Revance's Form 483 Response indicates that it had manufactured a new WCB that was undergoing qualification and that drug substance lots made with the "same process" were "manufactured successfully and met the acceptance criteria . . . [.]" Ex. C at 5. The *Zogenix* court explained that "were plaintiffs' version of falsity the law, a pharmaceutical company could be sued for securities fraud each and every time it received a [new drug application] rejection from the FDA[,] . . . [as] [p]otential plaintiffs could merely parrot any deficiency identified by the FDA rejection letter and then claim the company concealed from the market that it failed to include this 'necessary' piece of information in its application." 2020 WL 3820424, at *9. Similarly, Plaintiffs cannot rely on the FDA's statements in the Form 483 and the fact that the FDA ultimately denied the BLA to argue that Defendants concealed important information from investors. Thus, Plaintiffs' readiness statements in FAC ¶¶ 143-44 are not actionable. However, even if these statements were actionable, Plaintiffs have failed to allege scienter, which the Court addresses in Section 4 below.

c. Post-Inspection Statements

The FDA issued the Form 483 on July 2, 2021. Plaintiffs challenge the following post-

inspection statements as misleading for failure to disclose the Form 483 and the changed manufacturing process:

- "The FDA initiated their pre-approval inspection of our manufacturing facility in June, and we continue to anticipate approval of [DAXI] for Injection for the treatment of glabellar lines in 2021. We are actively preparing for the launch . . . [.]" FAC ¶ 150 (Aug. 5, 2021 Press Release); *see also* FAC ¶ 155.

- "[O]ur BLA may receive a Complete Response Letter or another response from the FDA identifying deficiencies that must be addressed, rather than an approval." FAC ¶ 152 (Aug. 5, 2021 Form 10-Q).

- "So we continue to feel very good that they're following sort of through with the expected inspection plan. I think you're sensing consistency with our tone around the expected approval before year-end. We've taken advantage of this time to keep up sort of our readiness for the inspection and continue to advance our commercial preparation plans." FAC ¶ 156 (Aug. 5, 2021 Q2 2021 Earnings Call)

- "[W]e're focused on an approval certainly before the end of 2021, and have full preparation and build schedule going on in the interim . . . [inspection] is a standard piece that needs to happen before approval. So the next communication you'll hear from us is kind of once we get the decision. But again, come back to the fact that we feel very good about our prep and where we were in that process . . ." FAC ¶ 157 (Aug. 5, 2021 Q2 2021 Earnings Call).

- "[W]e feel really good about where we are in that [approval] process. The last thing that had to be completed as part of our approval was the on-site inspection, which did happen at the end of [Q2]." FAC ¶ 159 (Sept. 9, 2021 Wells Fargo Conference).

- "A typical inspection is 1 to 2 weeks of sort of on-site inspection activities. Ours was a very typical inspection." FAC ¶ 161 (Sept. 9, 2021 Wells Fargo Conference).

- "[T]he company continues to anticipate FDA approval of [DAXI] in 2021. Revance notes that the issuance of a Form 483 following the conclusion of an onsite inspection is not uncommon. A Form 483 lists observations made by FDA representatives during the inspection of a facility. A Form 483 does not constitute a final agency determination. Revance provided its response to the Form 483 in July 2021 following a preapproval inspection and is currently awaiting the FDA's decision on its BLA for [DAXI]. The company remains confident in the quality of its BLA submission and continues to anticipate FDA approval in 2021." FAC ¶ 165 (Oct. 12, 2021 Press Release).

Defendants argue that these statements are not false or misleading because they do not refer to the outcome of the FDA inspection or state that Revance had not received a Form 483. Motion at 23-24. The Court agrees with Defendants that the statement that the inspection was

"typical" was not misleading. *See* FAC ¶ 161. Plaintiffs argue that the inspection was not "typical" in light of the "severity of certain Deficiencies identified in the Form 483 . . . [.]" Opposition at 20. However, this statement was made immediately after stating that "[a] typical inspection is 1 to 2 weeks," implying that the "typical" comment referred to the length of the inspection. *See* FAC ¶ 161. Moreover, Plaintiffs have not alleged that Form 483s are uncommon, or even that they necessarily result in a Complete Response Letter. Accordingly, this statement was not misleading.

Plaintiffs also contend that Revance's statement that it "may receive a Complete Response Letter or another response from the FDA identifying deficiencies that must be addressed, rather than approval," "put the Form 483 itself 'in play.' " Opposition at 18 (citing FAC ¶ 152). The Court agrees. Although Defendants were under no obligation to discuss the FDA process, once they chose to discuss the process, they were required to do so in a way that was not misleading. Stating that Revance "may" receive a response from the FDA identifying deficiencies was misleading where Revance did not disclose that these risks "may already have come to fruition." *See Berson*, 527 F.3d at 987-90; *see also Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d 1167, 1181 (9th Cir. 2009), *aff'd*, 563 U.S. 27 (2011) (misleading where the SEC Form spoke about the risks of product liability claims in the abstract when the company was already being sued in a product liability action). Moreover, at the inspection, the FDA assessor told Defendant Joshi (Revance's Chief Operating Officer and President of R&D and Products Operations) that the FDA recommended that the BLA be withheld for lack of commercial readiness. FAC, Ex. B at 2. Thus, at this point, it was misleading to tout Revance's confidence in BLA approval, and statements in FAC ¶¶ 150, 152, 155, 156, 157, 159, 165 may be actionable if Plaintiffs have alleged scienter, which the Court explores in Section 4, below.

d. Schilke and Joshi's Liability

Individuals are only liable for materially misleading or false statements that they "made." *Janus Cap. Grp., Inc. v. First Derivative Traders*, 564 U.S. 135, 141 (2011). A person or entity who has "ultimate authority over the statement" is said to have made the statement. *Id.* at 142. After *Janus*, courts have held that corporate officers who sign statements made with the SEC may

be said to have "made" the statement. *See Abdo v. Fitzsimmons*, No. 17-CV-00851-TSH, 2021 WL 616324, at *7 (N.D. Cal. Feb. 17, 2021); *Special Situations Fund III QP, L.P. v. Brar*, 2015 WL 1393539, at *3 (N.D. Cal. Mar. 26, 2015) ("Courts have consistently held that the signer of a corporate filing is its 'maker,' because signing a filing implies 'ultimate control' over its contents.") (citation omitted) (citing cases).

Defendants argue that Defendants Schilke (Revance's Chief Financial Officer) and Joshi did not make any of the challenged statements, and thus are not liable. Motion at 19 n. 2. Plaintiffs allege that Joshi effectively made several statements as he signed SEC filings that contain false or misleading statements. Opposition at 21 (citing FAC ¶¶ 123-24, 138-39, 152-53). Joshi may be held liable for false or misleading statements in SEC filings that he signed. *See Abdo*, 2021 WL 616324, at *7.

Plaintiffs also argue that Schilke and Joshi effectively "made" statements because they failed to correct false or misleading statements on conference calls that they attended. Motion at 21 (citing FAC ¶¶ 121-22, 126-29, 132-34, 144-45, 167). The Ninth Circuit has not determined whether an officer may be liable for failing to correct false or misleading statements. Some courts have held that a high-ranking officer may not "knowingly fail to correct" a false statement made by another official. *McGuire v. Dendreon Corp.*, No. C07-800MJP, 2008 WL 5130042, at *8 (W.D. Wash. Dec. 5, 2008) (citation omitted) (citing cases). Other courts have held that an officer is not liable for failure to correct another's statements without factual allegations demonstrating that the officer had "ultimate control and authority over those statements." *See Hampton v. Aqua Metals, Inc.*, No. 17-CV-07142-HSG, 2020 WL 6710096, at *17 (N.D. Cal. Nov. 16, 2020); *City of Royal Oak*, 880 F. Supp. 2d at 1071 (Board Chairman not liable under *Janus* for statements that other individual defendants made during investor calls). The Court finds persuasive the latter set of cases as they comport with the Supreme Court's requirement that "the maker of a statement is the person or entity with ultimate authority over the statement . . . [.]" *Janus*, 564 U.S. at 142. With the exception of the statements that Joshi signed, Plaintiffs have not alleged that Joshi had ultimate authority over any of the statements pleaded, and Plaintiffs have not alleged that Schilke had ultimate authority over any statements. Accordingly, Joshi and Schilke are not liable for

statements they did not correct. Plaintiffs may amend their pleadings to show that Joshi or Schilke had ultimate authority over the oral statements made on investor calls.

4. Scienter

Defendants also challenge the sufficiency of Plaintiffs' allegations with respect to scienter. Scienter is the intent to deceive, manipulate or defraud. *Tellabs,* 551 U.S. at 319. To establish scienter, the complaint must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u– 4(b)(2)(A). The required state of mind is "a mental state that not only covers 'intent to deceive, manipulate, or defraud,' but also 'deliberate recklessness.' " *Schueneman v. Arena Pharms., Inc.*, 840 F.3d 698, 705 (9th Cir. 2016) (internal citations omitted). Deliberate recklessness is "'an *extreme* departure from the standards of ordinary care,' which 'presents a danger of misleading buyers or sellers that is either known to the defendant or is so *obvious* that the actor must have been aware of it.'" *In re Alphabet, Inc. Sec. Litig.*, 1 F. 4th at 701 (emphasis in original) (quoting *Nguyen v. Endologix, Inc.*, 962 F.3d 405, 414 (9th Cir. 2020)).

The "strong inference" required by the PSLRA "must be more than merely 'reasonable' or 'permissible'—it must be cogent and compelling, thus strong in light of other explanations." *Tellabs*, 551 U.S. at 324. "Facts showing mere recklessness or a motive to commit fraud and opportunity to do so provide some reasonable inference of intent, but are not sufficient to establish a strong inference of deliberate recklessness." *In re VeriFone Holdings*, 704 F.3d at 701. "A court must compare the malicious and innocent inferences cognizable from the facts pled in the complaint, and only allow the complaint to survive a motion to dismiss if the malicious inference is at least as compelling as any opposing innocent inference." *Zucco Partners*, 552 F.3d at 991 (9th Cir. 2009); *see Nguyen*, 962 F.3d at 415 (9th Cir. 2020). In evaluating whether a complaint satisfies the "strong inference" requirement, courts must consider the allegations and other relevant material "holistically," not "scrutinized in isolation." *In re VeriFone Holdings,* 704 F.3d at 701-02 (citing *Tellabs*, 551 U.S. at 323, 326). Because scienter is a subjective inquiry, "the ultimate question is whether the defendant knew his or her statements were false, or was consciously reckless as to their truth or falsity." *Gebhart v. SEC*, 595 F.3d 1034, 1042 (9th Cir.

2010).

Plaintiffs rely on the following to support an inference of scienter: (1) Defendants' knowledge of and access to the deficiencies and the Form 483; (2) the core operations doctrine; and (3) Defendants' motives to artificially inflate its stock. Plaintiffs' scienter allegations fail for several reasons.

Plaintiffs detail Defendant Joshi's access to information about the BLA and the FDA approval process, FAC ¶¶ 183-187, and allege that Defendant Foley (Revance's Chief Executive Officer) and Defendant Schilke also had access to this information because Joshi reports to Foley, FAC ¶ 187, and these three Individual Defendants had weekly meetings, some of which related to FDA inspection preparations, FAC ¶ 189. However, Plaintiffs cite to no authority showing that simply reporting to another employee or having meetings about the general subject are sufficient to show knowledge. Indeed, "[w]here a complaint relies on allegations that management had an important role in the company but does not contain additional detailed allegations about the defendants' actual exposure to information, it will usually fall short of the PSLRA standard." *S. Ferry LP, No. 2 v. Killinger*, 542 F.3d 776, 784 (9th Cir. 2008) ("*Killinger*"). That is the case here.

Further, knowledge of manufacturing issues alone is insufficient to show intent to deceive or that Defendants were deliberately reckless. *See Connetics*, 542 F. Supp. 2d at 1008. With respect to pre-inspection statements, Plaintiffs have not made any allegations that Defendants had "contemporaneous knowledge" that a statement was false or misleading when made. *See VIVUS*, 2012 WL 4477647, at *19. Plaintiffs' theory is that Defendants knew of the existence of various deficiencies, and therefore their statements about FDA approval were misleading. However, Plaintiffs have not pointed to any evidence that Defendants believed that FDA approval was unlikely or would be delayed because of the deficiencies.

Moreover, the Court must weigh plausible competing inferences. *Tellabs*, 551 U.S. at 323-24. Plaintiffs contend that Defendants' awareness of the deficiencies shows scienter. Opposition at 26-29. However, the problem is that Plaintiffs only allege that in hindsight, after receipt of the Form 483, these deficiencies showed an intent to deceive. Even if Defendants' projections or

statements of confidence were overly optimistic, Plaintiffs have not alleged facts showing that Defendants believed that the manufacturing issues could not be resolved quickly or that the FDA would not approve the BLA.[4]

Plaintiffs argue that once Defendants knew that the WCB had deteriorated, that it would not be qualified until the end of 2021, and the FDA issued the Form 483, there is a strong inference of scienter. To sufficiently plead scienter for allegedly misleading omissions, however, Plaintiffs must allege "a highly unreasonable omission" and facts to support the inference that Defendants either knew that their omissions were misleading the investors or that the potential for misleading the public was so obvious that Defendants must have been aware of it. *See Zucco Partners*, 552 F.3d at 991. None of the facts alleged in the FAC relate to the Defendants' state of mind. Indeed, "even if a company knows that a problem exists, it could still honestly and in good faith report that the company will continue to perform as expected. Management simply may have been confident that they could overcome the problems or merely underestimated the severity of such problems." *Connetics*, 542 F. Supp. 2d at 1008 (quoting *In re CBT Group PLC Sec. Litig.*, 1999 WL 1249287 *3 (N.D. Cal. July 21, 1999)). As the pleadings show, Revance was in the process of qualifying a new WCB and had already successfully produced drug substance lots with the new WCB. Thus, there are no indications that Defendants intended to deceive investors by stating their readiness for BLA inspection or FDA approval. In. *Zogenix*, the court found insufficient allegations of scienter as "Plaintiffs have no answer to defendants' benign explanation—namely that 'Zogenix had every incentive to get it right the first time, and to put FINTEPLA on the path to [FDA] approval,' did not consciously engage in any 'reckless gamble,' but rather misread what the FDA was looking for in the FINTEPLA NDA." 2020 WL 3820424, at *11. The same is true here. Although Plaintiffs argue that Defendants knew or recklessly disregarded information that "materially decreased the likelihood that the BLA would be approved as submitted," Opposition at 29, the FAC does not allege an intent to deceive, manipulate, or

[4] Plaintiffs also argue that Defendants were aware of the lack of the QA. Opposition at 27. However, as discussed above in Section 3(a), the fact that the QA was quickly resolved after the Form 483 observation suggests that failure to disclose the lack of a QA was not material.

defraud investors. Indeed, the Form 483 is not a final determination by the FDA, and although evidently Revance's Form 483 Response did not satisfactorily address the FDA's concerns, Defendants' misreading of what the FDA required does not show conscious intent to deceive or an "extreme departure from the standards of ordinary care." *See In re Alphabet, Inc. Sec. Litig.*, 1 F. 4th at 701; *Zogenix*, 2020 WL 3820424, at *11.

Further, the statements that Plaintiffs cite – projections for the timeline for approval, confidence in the BLA submission, and readiness for inspection – were not "so dramatically false" that at least some corporate official must have known of their falsity upon publication. *See In re NVIDIA Corp. Sec. Litig.*, 768 F.3d 1046, 1063-64 (9th Cir. 2014) (awareness of serious defects in two important products was not enough to trigger corporate scienter). The more compelling inference is that Revance believed it was on the path to approval, even after the issuance of the Form 483, which is supported by the fact that the FDA approved the BLA the following year. FAC ¶ 23. Accordingly, Plaintiffs have not pleaded scienter based on Defendants' purported knowledge of manufacturing issues.

Plaintiffs' core operation allegations are also deficient. The "core operations" doctrine allows the knowledge of certain facts that are critical to a business's "core operations" to be attributed to a company's key officers. *Webb v. Solarcity Corp.*, 884 F.3d 844, 854 (9th Cir. 2018). "Allegations that rely on the core-operations inference are among the allegations that may be considered in the complete PSLRA analysis." *Killinger*, 542 F.3d at 784. "[C]orporate management's general awareness of the day-to-day workings of the company's business does not establish scienter—at least absent some additional allegation of specific information conveyed to management and related to the fraud." *Metzler*, 540 F.3d at 1068. Plaintiffs argue that it would be "absurd to suggest" that Defendants were unaware of the deficiencies and the Form 483 while making positive statements about the BLA and FDA inspection and approval timeline. Opposition at 30. However, Plaintiffs have not made "detailed and specific allegations" supporting a strong inference that Defendants Schilke or Foley were intimately involved in the minutiae of the BLA process. *Zucco Partners*, 552 F.3d at 1000 (citation omitted). The fact that Defendants had "some" meetings about the BLA and FDA approval process does not plausibly allege that specific

information was conveyed to Foley or Schilke. *See In re NVIDIA Corp.*, 768 F.3d at 1064. Even assuming that knowledge could be imputed on the Individual Defendants under the core operations doctrine, Plaintiffs again fail to show that knowledge of manufacturing deficiencies meant that Defendants believed that the BLA was not ready or would not pass inspection, and thus fail to show scienter under the core operations theory.

Plaintiffs also argue that Defendants had "compelling motives" to mislead investors to keep stock prices inflated during the class period as their compensation came in the form of stock and options. Opposition at 30-31 (citing FAC ¶¶ 212-13). But "evidence of a personal profit motive on the part of officers and directors . . . is insufficient to raise a strong inference of scienter." *Intuitive Surgical*, 759 F.3d at 1064 (significant profits from sale of company stock did not raise an inference of scienter); *see In re Rigel Pharms., Inc. Sec. Litig.*, 697 F.3d 869, 884 (9th Cir. 2012) ("allegations of routine corporate objectives such as the desire to obtain good financing and expand are not, without more, sufficient to allege scienter"). Moreover, Plaintiffs fail to acknowledge that the Ninth Circuit has "recognized that a lack of stock sales can detract from a scienter finding." *Webb*, 884 F.3d at 856. None of the Individual Defendants is alleged to have sold Revance stock during the class period. *See In re Pixar Sec. Litig.*, 450 F. Supp. 2d 1096, 1107 (N.D. Cal. 2006) ("the absence of insider trading by a defendant is highly relevant and undermines any inference of scienter"). In *Nguyen*, the Ninth Circuit found that the plaintiffs' theory that defendants promised FDA approval that they knew would not be approved because of migration problems "does not make a whole lot of sense," and relies on the "supposition that defendants would rather keep the stock price high for a time and then face the inevitable fallout" when the migration problem was revealed. 962 F.3d at 415. However, there were no factual allegations that the defendants sold any stock or sold the company at a premium during this time. *Id.* Thus, the court found the allegations of fraud implausible. *Id.* The same is true here. Therefore, the Court finds that Defendants' general financial motives cannot show scienter. *See id.* ("Treating the allegations in the complaint in the light most favorable to the plaintiff, the notion that a company would promise FDA approval that it knew would not materialize does not, without more, create a strong inference of intent to deceive or deliberate recklessness.").

After having determined that none of Plaintiffs' allegations, standing alone, is sufficient to create a strong inference of scienter, the Court now considers the allegations holistically. *See In re VeriFone*, 704 F.3d at 702–03; *Zucco Partners*, 552 F.3d at 992. The Court finds that taken together, the facts do not evince such fraudulent intent or deliberate recklessness as to make the inference of scienter cogent. *See Tellabs*, 551 U.S. at 323-24. Indeed, as noted above, Plaintiffs' factual allegations fail to sufficiently plead scienter as to any of the Defendants. Accordingly, the Court **DISMISSES** the FAC with leave to amend.

C. Section 20(a) Claim

A Section 20(a) claim requires an underlying violation of securities law. *In re Rigel Pharms.*, 697 F.3d at 886. Because Plaintiffs failed to adequately plead a violation under Rule 10b-5/Section 10(b), their Section 20(a) claim also fails. *See id.*

IV. CONCLUSION

For the foregoing reasons, the Court **GRANTS** Defendants' motion to dismiss with leave to amend. Any amended complaint must be filed by **May 1, 2024**. No additional parties or claims may be added without leave of Court or stipulation of Defendants.

IT IS SO ORDERED.

Dated: March 30, 2024

ARACELI MARTÍNEZ-OLGUÍN
United States District Judge